REMARKS

Claims 16 and 75-76 have been amended.

In the Office Action, the submitted Forms PTO-1449 were signed, but some references were not initialed. An initialed Form PTO-1449 is respectfully requested for the following Forms PTO-1449:

Form PTO-1449 dated:	Reference not initialed:
April 29, 2005	"510(k) Notification for the Cardica C-Port Anastomosis System," Section 9, "Substantial Equivalence," and Appendices B, C, E, (Unpublished)
January 27, 2006	US 2005/0267496 US 4241861

To the extent that it is not necessary to address the rejection of dependent claims by the Office Action in order to provide a complete response, the choice not to discuss such rejections is not, and cannot be interpreted as, acquiescence to such rejections, nor does it limit or can it be construed during prosecution of this patent application or in any later administrative or judicial action to limit the scope of any claims that may eventually issue in this patent application or in any patent application claiming priority to this one.

35 U.S.C. §112

Claim 76 has been amended to correct a typographical error.

It is unclear if claims 16 and 75-76 have been rejected under 35 U.S.C. §112, because the Office Action indicates that the Examiner "will interpret the claim as the shield is made of a deformable material, and thus is deformed upon removal."

Such an interpretation of the language is what is claimed, and both that interpretation and the plain language of the claim are supported by the specification:

> "When the anvil arm 14 is withdrawn from the anvil entry hole 584 in the target vessel 580, the shield 290 (if utilized) slides out of the heel 587 of the anastomosis. The shield 290 is sized and shaped such that it

> can exit through the heel 587 without substantially disturbing the anastomosis. For example, the shield 290 may be thin and narrow, and flexibly connected to the anvil arm 14, such that it can slip out of the heel 587 substantially without affecting the tissue of the graft vessel 404 or the target vessel 580 and substantially without resulting in leakage at the heel 587. Further, the shield 290 may be composed of a flexible material such as polyethylene that facilitates the flexing and removal of the shield 290 from the anastomosis." (page 147, line 23 through page 148, line 7).

Thus, the specification discloses that flexing – that is, deformation – of the shield facilitates removal of the shield from the anastomosis, as claimed in claims 16 and 75-76. Nevertheless, claims 16 and 75 have been amended without changing their scope, in order to facilitate prosecution.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 12, 15-16, 68-71, 73-74

The rejection of these claims is respectfully traversed.

Claim 12 claims, among other elements, "placing a shield between the end of the graft vessel and the side of the target vessel, wherein said shield is connected to said anvil; and moving a cutter to incise the target vessel, wherein said shield protects the graft vessel from the cutter." "[A]s as the staple holder 38 and the anvil 10 move toward the closed position the shield 290 remains outside the target vessel 580, between the end of the graft vessel 404 and the outer surface of the target vessel 580." (Specification; page 115, lines 1-3; Figure 95) (emphasis added). "[T]he shield 290 holds the tissue of the graft vessel 404 away from the path of motion of the projection 208 [of the cutter 200] to

minimize or eliminate contact between the projection 208 and the graft vessel 404," thereby protecting the graft vessel 404 from the cutter. (Specification; page 139, lines 16-23).

In contrast, U.S. Pat. No. 6,187,019 to Stefanchik et. al. ("Stefanchik") does not disclose a shield at all, much less "placing a shield between the end of the graft vessel and the side of the target vessel…wherein said shield protects the graft vessel from the cutter." First, the Office Action characterizes the tissue clamps 50, 52 of Stefanchik as analogous to the claimed shield. (Office Action, page 3). However, the clamps 50, 52 are not shields, and shield nothing. much less the graft vessel. Instead, the clamps 50, 52 simply "bear against the sides of the graft blood vessel 152 to help align and hold the graft vessel in the location shown," as one would expect clamps to do. (Stefanchik; col. 7, lines 4-6).

Second, the tissue clamps 50, 52 do not "protect[] the graft vessel from the cutter," as required by claim 12. Indeed, no structure of Stefanchik protects the graft vessel from a cutter. To the extent that Stefanchik discloses a cutter at all, the plow 110 includes two cutting edges 116, 118 near its pointed end. (Stefanchik; col. 7, lines 58-63). In use, "these cutting edges incise the tissue of the graft and target blood vessels." (Stefanchik; col. 7, lines 59-63; Figure 17) (emphasis added). Thus, not only does Stefanchik not protect the graft vessel from a cutter, it affirmatively requires a cutter to incise the graft vessel during actuation of the tool.

Third, the clamps 50, 52 are located to the side of the graft vessel, outside of both the graft vessel and the target vessel. (Stefanchik; Figures 2, 3, 7, 8-11,15-16, 19, 20; especially Figure 11). As a result, no part of the clamps 50, 52 is, and no part of the clamps 50, 52 can be, located "between the end of the graft vessel and the side of the target vessel" as required by claim 12.

Fourth, Stefanchik fails to disclose an anvil, as required by claim 12. The Office Action identifies the prong 82 of Stefanchik as analogous to the claimed anvil. (Office Action, page 3). The specification of the present application utilizes the term "anvil" in the same manner as its standard usage in the art: an anvil is a structure against which connectors are deformed. (Specification; *e.g.*,

page 21, lines 13-21; page 120, line 19 through page 121, line 6). However, the prong 82 of Stefanchik merely holds the tissue of the target vessel 150. (Stefanchik; *e.g.* Figure 5). No connectors are deformed against the prong 82, and indeed even the spiral needles 161, 162 that carry suture 161 do not contact it; instead, grooves 120 in the plow 110 guide the needles 161, 162. (Stefanchik; col. 7, lines 52-64; Figures 13-14, 17). Indeed, the word "anvil" does not appear even once in the specification of Stefanchik.

Fifth, claim 12 requires the shield to be connected to the anvil. Because Stefanchik does not describe an anvil, it cannot describe a shield connected to an anvil. Further, the tissue clamps 50, 52 of Stefanchik attach to the frame 40 of the tool, not to an anvil. (Stefanchik; col. 6, lines 23-28; Figure 7).

Thus, Stefanchik neither expressly nor inherently discloses each and every element claimed in claim 12, and claim 12 is believed to be in condition for allowance. Claims 15-16, 68-71, 73-74 depend from claim 12, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With reference to dependent claim 69, as stated above, the tissue clamps 50, 52 are not and cannot be the claimed shield. Even if the prong 82 of Stefanchik were to be considered analogous to the claimed anvil, which it is not (as set forth above), the notches in the tissue clamps 50, 52 are oriented at a right angle to the prong 82, such that they are not and cannot be "substantially aligned with said channel" in the anvil as required by claim 69.

With regard to dependent claim 73, the interpretation of the term "substantially" improperly reads the claim limitation "substantially simultaneously" out of the claim. No evidence or analysis is given for the assertion that the term "substantially simultaneously" "may encompass a time period including the time period of the procedure."

Claims 75-76

The rejection of these claims is respectfully traversed.

The Office Action analogizes the claimed shield to the balloon anvil 560 of U.S. Patent No. 6,248,117 to Blatter ("Blatter"). (Office Action, page 5). That is, the balloon anvil 560 is simply another embodiment of the "intraluminally directed anvil apparatus" of Blatter. (Blatter; e.g., col. 24, line 62 through col. 25, line 65; Figures 17A-17B). The Office Action points to Figures 15d, 15h and 15k in support of this rejection. (Office Action, page 5). However, the cited balloon anvil 560 appears nowhere in these figures. Instead, these figures describe a solid anvil 160. (Blatter; *e.g.*, col. 22, lines 29-43; Figures 15A-15K). According to Blatter, "[t]he term 'anvil' in the context of this invention is meant to encompass balloon anvils" such as balloon anvil 560. (Blatter; col. 25, lines 64-65). That is, the balloon anvil 560 is a different embodiment of the anvil than the solid anvil 160. The balloon anvil is puncture-resistant. (Blatter; col. 23, lines 56-57).

Claim 75 requires "placing a shield between the end of the graft vessel and the side of the target vessel." In contrast, every embodiment of the anvil of Blatter – whether the solid anvil 160 or the balloon anvil 560 – is located inside the target vessel and adjacent to the target vessel wall, with the graft vessel outside the target vessel wall. (Blatter; especially Figures 15E and 17C). That is, the target vessel separates the anvil 160, 560 from the graft vessel. Blatter nowhere describes a shield that is "between the end of the graft vessel and the side of the target vessel." For this reason alone, Blatter does not describe each and every element of claim 75.

In addition, claim 75 requires "moving a cutter to incise the target vessel, wherein said shield protects the graft vessel from the cutter." Because every embodiment of the anvil 160, 560 of Blatter is located inside the target vessel, separated from the graft vessel by the target vessel wall, the anvil 160, 560 of Blatter does not and cannot protect the graft vessel from a cutter, as required by claim 75.

Thus, Blatter neither expressly nor inherently discloses each and every element claimed in claim 75, and claim 75 is believed to be in condition for allowance. Claim 76 depends from claim 75, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 76, the anvil of Blatter is moved intraluminally through the vasculature to the anastomosis site; it is not inserted through the side of the target vessel as required by claim 76. (Blatter; *e.g.*, col. 17, lines 18-27). Indeed, in Blatter "[t]he distal end of the catheter wire is pushed along one of the catheter lumens so the wire's distal end pierces the wall of the receiving blood vessel from the intima outward through the media and adventitia." (Blatter; *e.g.*, col. 17, lines 19-22) (emphasis added).

Further, dependent claim 76 expressly requires an anvil in addition to the shield. The item 554 identified as being analogous to the shield is in fact a piercing wire 554 attached to the anvil 560. (Blatter; e.g., col. 24, lines 62-66). The anvil of Blatter cannot be analogous both to an anvil and a shield that is claimed separately from that anvil.

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

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